Comments on the Medicaid Managed Care Rule

October 19, 2001

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INTRODUCTION

The Balanced Budget Act of 1997 (BBA) established a new playing field for managed care organizations in Medicaid. In exchange for allowing states broader flexibility to enroll Medicaid patients in managed care plans, Congress required states to adopt important patient protections. The BBA established rules governing the quality of care, protecting patients with special health care needs, guaranteeing the provision of necessary information to patients about their health plans, insuring recourse through a grievance system, and protecting enrollees against fraud and abuse. These protections were consistent with longstanding provisions in the Social Security Act (Act) that protect Medicaid enrollees through numerous safeguards.

The January final rule realized these statutory mandates through reasonable regulations and protections. For example, the rule consistently defined ambiguous terms, like "special health care needs," to ensure that patients received the protections created for them in the BBA and in the Act. In addition, the January rule was generally consistent with Medicare+Choice regulations and was informed by key consensus-oriented reports, including the findings of the President's Commission on Consumer Protection and Quality in the Health Care Industry and the HHS document *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (known as the "Special Needs Report"). The January rule was reasonable; it struck a balance between the needs of patients and the burdens on health plans while providing the protections demanded by the BBA and the Act.

The proposed rule, by contrast, represents a profound failure to provide patient protections. It fails to protect those with special health care needs, fails to define ambiguous terms, fails to require provision of necessary information, and generally fails to regulate. In many cases, the proposed rule takes the statutory requirements and passes them on to states and plans without guidance, giving states and managed care plans the opportunity to abandon patient protections by narrowly construing the requirements and putting them at risk of litigation on grounds of misinterpretation.

These failures violate the spirit and, often, the letter of both the BBA and the Act. Moreover, these failures are bad policy. In many cases, the proposed rule's provisions are inconsistent with the findings of major governmental and nongovernmental reviews, contradict extensive research, and do not even meet the patient protection standards set by H.R. 2563 as passed by the House, the "patients' bill of rights" that President Bush has endorsed.

The proposed rule also violates the Administrative Procedures Act, because the Administration has not adequately explained its numerous reversals from the

January final rule. As the Supreme Court has made clear, an agency changing its course is obliged to supply a reasoned analysis for the change. Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983). As other courts have explained, "an agency may not repudiate precedent simply to conform with a shifting political mood. Rather, the agency must demonstrate that its new policy is consistent with the mandate with which *Congress* has charged it." National Black Media Coalition v. FCC, 775 F.2d 342, 356 N.17 (D.C. Cir. 1985). Moreover, the agency must base the change on evidence from the rulemaking record. These things the agency has wholly failed to do.

The preamble, the place where agency action is to be explained, is devoid of explanations for the amendments. Other than in the beginning, where it acknowledges that it is amending a rule, the preamble nearly ignores that it is changing an existing regulation. It rarely mentions the January final rule let alone why it is making the changes that it does. In the comments below, we point out a number of places where the agency has proposed to alter the regulations of the January final rule without explanation.

There are many other places in the proposed regulation that amend the January regulation without explanation that we have not pointed out. If the agency chooses not to replace the requirements deleted from the January final rule, as we argue below that it should, at the very least, it must explain each of these changes and demonstrate what in the rulemaking record justifies the change.

We urge the agency to reinstate many aspects of the January final rule. The January final rule better effectuated the BBA and the Act. Our comments below are organized into six sections.

- First, we argue that prepaid ambulatory health plans should not be exempted from core patient protections.
- Second, we call for numerous improvements to the regulations dealing with the grievance and appeals process.
- Third, we seek substantial changes in provisions relating to special populations, including individuals with special health care needs, members of ethnic and racial minority groups, and residents of rural areas.
- Fourth, we detail needed improvements in provisions related to health care quality.
- Fifth, we propose changes related to sections of the proposed rule on information for enrollees.
- Sixth, we note several other provisions of the rule that need to be altered to be consistent with good policy, the Act and the BBA.

I. AMBULATORY HEALTH PLANS SHOULD NOT BE EXEMPT FROM ESSENTIAL PATIENT PROTECTIONS

A Prepaid Ambulatory Health Plan (PAHP) is defined in § 438.2 of the proposed rule as an entity that:

> (1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;
> (2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and
> (3) Does not have a comprehensive risk contract.

While according to the proposed rule's preamble, a PAHP can be organized to provide dental care or transportation,[1] it is also evident that the definition includes more comprehensive plans. For example, any plan that provides only outpatient treatment – such as primary care services, mental health services, reproductive health care, or HIV services – could qualify as a PAHP. Indeed, a plan could provide *all care* except inpatient services and be a PAHP. Yet, despite the fact that patients may receive a large majority of their health care from PAHPs, the proposed rule arbitrarily exempts these plans from essential protections.

We believe that ambulatory and community-based health plans should not be exempt from core patient protections. Indeed, historically, regulations have applied basic protections to all prepaid health plans,[2] and the January final rule made no distinction between inpatient and outpatient plans. A state should be able to relax individual rules in clear cases of inapplicability, with justification to CMS. This is not a premise alien to the proposed rule; in § 438.208, for example, states can exempt plans from certain requirements if a determination is made that the "scope of services" is outside the relevant area. A parallel provision should be added to allow exemption with justification for ambulatory plans.

As the proposed rule stands, however, multiple blanket exemptions for ambulatory plans remove key patient protections.

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[1] 66 Fed. Reg. 43,614, 43,620 (Aug. 20, 2001).

[2] *See,* 42 C.F.R. 434.20-34.

A. Advance Directives (§ 438.6)

The proposed rule requires managed care organizations and inpatient prepaid plans to "provide adult enrollees with written information on advance directives policies, and include a description of applicable State law." However, this provision does not apply to PAHPs (also referred to as "ambulatory plans"), which may include primary care plans.

This exclusion makes no sense. No clinician is better placed to discuss advanced directives, which may avoid unnecessary, painful and expensive medical services, than the patient's primary doctor. It has been demonstrated that such discussions are valuable in the context of the doctor-patient relationship.[3]

> **Section 438.6**: Provisions on advance directives should apply to ambulatory plans. States should be allowed to make exempt those plans that may have no relevance to advance directives with justification to CMS.

B. Access to Medical Records (§ 438.100)

The proposed rule requires that inpatient plans, but not ambulatory plans, must provide enrollees with copies of their medical records. The exception for ambulatory plans is arbitrary, as the right of access to medical records is no less important simply because care was provided on an outpatient basis. Those ambulatory plans that keep medical records should be required to provide them to enrollees.

> **Section 438.100**: Provisions on medical records should apply to ambulatory plans.

C. Quality Improvement (§ 438.200-438.206 and § 438.236-242)

Subpart D of the proposed rule sets out standards "to ensure the delivery of quality health care." However, these standards do not cover the quality of care

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[3]W. Tierney, P. Dexter, G. Gramelspacher, A. Perkins, X Zhou, F. Wolinksy, *The Effect of Discussions About Advance Directives on Patients' Satisfaction with Primary Care*, Journal of General Internal Medicine, 32-40 (January 2001). ("Patients with chronic illnesses were more satisfied with their primary care physicians and outpatient visits when advanced directives were discussed.")

provided by PAHPs, which are exempted entirely from the rules.

As a result, states do not have to develop a strategy for "assessing and improving the quality" of ambulatory medical, mental health, and dental plans. Nor do states have to conduct reviews of quality, support the development of information systems to manage quality, create performance measures, or establish practice guidelines that "are based on valid and reliable clinical evidence." In fact, there is no required state oversight of the quality of care provided by PAHPs. This is a loophole that would allow plans to configure themselves as PAHPs to evade quality oversight.

> **Sections 438.200-206 and 438.236-242**: Provisions on quality improvement and oversight should apply to ambulatory plans.

D. Access Standards (§ 438.206)

The proposed rule requires states to "ensure that all covered services are available and accessible to enrollees." While this general statement includes the care provided by ambulatory plans, such plans are exempt from all specific access standards.

As a result, ambulatory plans are not specifically required to maintain and monitor an appropriate network, provide women with access to a woman's health specialist (in an outpatient medical plan), provide for second opinions, make services available 24 hours a day, 7 days a week, when medically necessary, or participate in the state's efforts regarding culturally competent care. Yet such efforts may be critically important for ambulatory plans. Indeed, some of these provisions – such as the right to a woman's health specialist – may *only* be relevant in some states for ambulatory plans.

> **Section 438.206**: Provisions on access standards should apply to ambulatory plans.

E. Adequate Capacity (§ 438.207)

The proposed rule requires that plans assure the state that there is adequate capacity to provide covered services. Again, however, ambulatory plans are arbitrarily made an exception. Dental plans, transportation plans, primary care plans, reproductive health plans, HIV plans, and other outpatient medical and mental health plans are thus under no obligation to show that they can actually provide promised care to enrollees. This is an arbitrary failure to assure even minimal services for Medicaid patients.

Section 438.207: Provisions on adequate capacity should apply to ambulatory plans.

F. Care for Individuals with Special Health Care Needs (§ 438.208)

While the proposed rule strikes many of the protections for individuals with special health care needs, the few that remain do not apply to ambulatory plans. PAHPs do not have to provide direct access to specialists, assist enrollees with special health care needs, develop treatment plans with enrollee participation, or coordinate care.

Such protections are critically important for ambulatory plans. For example, individuals with special health care needs frequently require extra attention from dental plans,[4] which the administration gives as an example of a PAHP. Similarly, young adults with developmental disabilities often need help coordinating between medical providers and scheduling appointments. The proposed rule provides no guarantees in these areas. Moreover, PAHPs are not limited to dental plans. Outpatient medical and mental health PAHPs would be allowed to deny patients these rights across a wide spectrum of medical care.

This omission is particularly inappropriate because individuals with special health care needs rely on ambulatory care to stay out of the hospital. By eliminating protections for these individuals outside the hospital, the proposed rule risks greater expense from increased hospitalizations.

Section 438.208: Provisions on care of individuals with special health care needs should apply to ambulatory plans.

G. Coverage and Authorization of Services (§ 438.210)

The proposed rule exempts ambulatory plans from contract requirements relating to the protection against arbitrary denials of care, written policies and procedures, guarantees that reviewers of care denials will be qualified, and promises that decisions on lifesaving care will be made promptly. All of these factors are essential for dental PAHPs (which may provide lifesaving dental treatments), transportation PAHPs (which may be responsible for transporting patients to lifesaving medical appointments), primary care plans, mental health plans, reproductive health plans, HIV plans, and other potential PAHPs that might provide outpatient medical or mental health coverage.

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[4]U.S. Surgeon General, *Oral Health in America* (2000).

Section 438.210: Provisions on coverage and authorization of services should apply to ambulatory plans.

H. Provider Selection (§ 438.214)

There are no credentialing requirements in the proposed rule for ambulatory plans. As a result, there is no oversight as to the quality of providers in such plans. Providers in these plans may be responsible for surgery, psychotherapy, and other forms of invasive treatment. Quality oversight is as essential as with any inpatient service.

Section 438.214: Provider selection provisions should apply to ambulatory plans.

I. Confidentiality (§ 438.224)

Under the proposedr ule, states are not responsible for violations of confidentiality by ambulatory plans. This could be a particularly important loophole if ambulatory mental health plans, HIV plans or reproductive health plans form in response to the regulations. It is also important for transportation plans. Breach of transportation records documenting transport to an HIV or reproductive health clinic is scarcely different from breach of medical records at the clinic – either could lead others to recognize the diagnosis. As the President's Commission on Consumer Protection and Quality in the Health Care Industry concluded, "To the maximum extent feasible in all situations, nonidentifiable health care information should be used unless the individual has consented to the disclosure of individually identifiable information."[5]

Section 438.224: Confidentiality provisions should apply to ambulatory plans.

J. Grievance System (§ 438.228)

The proposed rule does not require ambulatory plans to have to establish any grievance system. Given that these plans may provide critical services, including essential primary care, mental health, HIV and reproductive health care, this loophole is very troubling. Moreover, this omission is exacerbated by Section

[5]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

438.10, which exempts ambulatory plans from providing information on state fair hearing requirements or on any procedures to allow providers to appeal denials of care. The net result is that enrollees may believe that they have no recourse both inside and outside the plan, fundamentally undermining the Social Security Act's guarantee of patient rights.

> **Section 438.228**: Provisions on grievance should apply to ambulatory plans.

K. Subcontractor Relationships (§ 438.220)

Under the proposed rule, ambulatory plans are not responsible for the functions delegated to a subcontractor, do not need to have written agreements with subcontractors and do not have to monitor the subcontractor's performance. This arbitrary omission would allow fraud to go unchecked. For example, a transportation plan that subcontracts with a taxi company does not have to have a specific agreement on what that company must do. As prior problems in Virginia have illustrated, such oversight of subcontractors in transportation plans is essential.[6] Whether enrollees can get to the doctor can be a matter of life and death.

> **Section 438.220**: Provisions on subcontractor relationships should apply to ambulatory plans.

L. Program Integrity and Certification (§ 438.600-608)

The proposed rule exempts ambulatory plans from measures to root out fraud and abuse and from certifications about data used to justify state payments. As there can be significant fraud and abuse in ambulatory plans, exempting them is inconsistent with the goal of responsible program management.

> **Sections 438.600-608**: Provisions on program integrity and certification should apply to ambulatory plans.

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[6] *Medicaid Transport Problems Persist*, Richmond Time-Dispatch, B-1 (August 31, 2001) ("To reduce fraud and abuse, the Medicaid program switched to a subcontracted transportation system July 1, but many recipients were initially left scrambling for services when one of the companies hired to arrange car and van trips for clients could not meet demand.").

II. GRIEVANCE AND APPEAL PROTECTIONS MUST BE STRENGTHENED

In enacting the BBA, Congress specifically required health plans to establish internal grievance systems.[7] Such systems are vital to quality services in managed care because the health plan otherwise makes all of the decisions about the enrollees' health care. Unfortunately, the proposed rule arbitrarily weakens many key elements of the grievance and appeal process.

A. Information Requirements

A grievance system is only effective if enrollees know their rights and know how to enforce them. In the preamble, the agency acknowledged that enrollees cannot "effectively access their benefits if they are not furnished adequate information concerning these fundamental elements as enrollees' rights and responsibilities."[8] The proposed rule, however, deletes many requirements in the January final rule requiring health plans to tell enrollees about their rights.

1. Information About an Enrollees Right to Representation and Not to Suffer Retaliation (§ 438.10)

Both the January final rule and the proposed rule require health plans to provide information about the grievance and appeal system to enrollees, providers, and subcontractors.[9] In addition, both regulations also require the health plan to provide information to enrollees when it sends out a notice of action. (The notice of action is the official notification to the enrollee that some measure of their service is being denied.) However, the proposed rule deletes two important safeguards that were in the January final rule.

First, the proposed rule deletes a requirement in the January final rule that the health plan inform enrollees about their right to representation. The proposed rule does not alter the enrollees' right to have a representative. Indeed, multiple

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[7]Section 1932(b)(4) of the Act.

[8]66 Fed. Reg. at 43,624.

[9]66 Fed. Reg. 6228, 6422 (to be codified at 42 C.F.R. Pt. 438) (hereinafter "Jan Final Rule"); 66 Fed. Reg. at 43,663 (to be codified at 42. C.F.R. Pt. 438) (hereinafter "Proposed Rule").

parts of the proposed rule refer to the enrollees' right to a representative.[10] Instead, the proposed regulation simply delete the enrollees' ability to find out about that right. These are complicated proceedings involving difficult to understand rules and regulations. It is likely that an enrollee will need assistance in filing an appeal, but they may not be aware that this is an option for them. Failing to inform them of this right could effectively deny them counsel. The proposed rule does not explain why this requirement was deleted, nor can any reason be discerned.

Second, the proposed rule also deletes the requirement that health plans tell enrollees that they will not be negatively affected if they file an appeal or request a state fair hearing. As with the right to representation, the proposed regulation does not remove an enrollees' protection against retaliation for filing an appeal or grievance. But failing to assure enrollees of this protection will inevitably result in enrollees forgoing appeals out of fear of retaliation. Again, the proposed regulation arbitrarily deletes this important protection without explanation.

Each of these requirements provides valuable information to enrollees that will benefit them greatly. And each requirement comes at almost no cost to health plans who need only include information in materials that they are already required to provide. These deletions provide no benefit and only serve to lessen enrollees' motivation and ability to assert their rights effectively.

> **Section 438.10** Health plans should be required to inform enrollees that they have a right to representation and that they will not suffer from retaliation for filing an appeal or a grievance.

The proposed rule's failures to require information for enrollees are duplicated in failures to require information for providers and subcontractors. The agency rightfully recognizes the importance of providers and subcontractors understanding the rights of enrollees in the grievance system; the entire purpose of § 438.414 in the proposed rule is to tell them about enrollees' rights. The right to representation and to not suffer retaliation are important rights that should be included in that information, but are not. As with other information requirements, it does not cost health plans anything to inform providers and subcontractors of these rights and it is of enormous benefit to the enrollees. This amendment was unjustified.

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[10] *See, e.g.*, Proposed Rule § 438.406(b)(3) and (4); Proposed Rule § 438.408(c)(2).

Section 438.414 The regulation should be amended to require health plans to provide information to providers about an enrollee's right to have representation and to not suffer retaliation for filing an appeal or grievance.

2. Information about the Right to Present Evidence (§ 438.404)

The proposed rule deletes the requirement from the January final rule that health plans tell enrollees that they have a right to present evidence and provide instructions on how to go about obtaining it. While lawyers may recognize that evidence will be important in an appeal, many Medicaid beneficiaries may not. Deleting the requirement that health plans tell them about their right to present evidence may mean that they will be unaware of the right. Certainly health plan officials know that they can present evidence, and they will. Enrollees should be told about it so that they can present evidence as well.

Section 438.404 Health plans should be required to explain in the notice of action that enrollees have a right to present evidence and provide information on how to obtain it.

3. Followup of Oral Inquiries (§ 438.406)

Both the January final rule and the proposed rule allow beneficiaries to file appeals orally. Indeed, both rules appropriately provide that "oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal)." Both also require enrollees to follow up the oral request in writing.[11] The January final rule required health plans to inform enrollees that oral appeals must be followed up in writing. This is important because enrollees could quite reasonably assume that once they have conveyed their appeal, the plan must act.

The proposed rule, however, inexplicably deletes this requirement, potentially leaving many beneficiaries to believe that they have begun an appeal only to discover later the complaint has languished for want of a written follow-up. This information is of enormous benefit to the enrollee and comes at almost no cost to health plans. The agency gives no reason for deleting this requirement and it is difficult to imagine what could justify the change.

[11]Oral requests for expedited appeals need not be followed up in writing.

Section 438.406 Health plans should be required to inform the enrollee that an oral appeal must be followed up in writing.

B. Timeframes

1. Extension of Timeframes for Resolution of Appeals (§ 438.408)

Under both the January final rule and the proposed rule, health plans may extend the deadline for responding to an enrollee's appeal. The proposed rule, like the January final rule, requires health plans to inform the beneficiary of the reason for the delay. The proposed rule, however, deletes the requirement that health plans inform enrollees of their right to file a grievance if they disagree with the health plan's decision to extend the deadline to respond to an appeal. This is a serious omission because, under the proposed rule, health plans can unilaterally extend the deadline in every type of appeal, even those where the enrollee's health is potentially in serious jeopardy. Health plans need not ask enrollees; they need only inform them. Moreover, as discussed below, health plans can continue to extend the deadline again and again, making the grievance right that much more important.

Requiring information on this grievance right affords significant benefits to the enrollee without imposing any significant costs on health plan.

Section 438.408 Health plans should be required to tell enrollees about their right to file a grievance when the health plan extends the time to respond to an appeal.

2. Time to Resolve Standard Appeals (§ 438.408)

Both sets of regulations establish deadlines by which a health plan must respond to appeals. Under the January final rule, health plans had 30 days. The proposed rule extends this deadline, allowing health plans 45 days to resolve appeals. The reason for the additional 15 days is not given.

Section 438.408 The time for responding to a standard appeal should be 30 days.

3. Extension of Timeframes (§ 438.408)

As discussed above, health plans are allowed to extend the time that they have to respond to appeals and grievances. The proposed rule contains the same

basic framework as the January final regulation but it differs in two important respects. The first is in how it treats extensions for expedited appeals. This change is discussed below in Section C.

The second change is subtle, but drastic: It allows the health plan to grant itself unlimited extensions. Both regulations allow the health plan to extend the timeframe for standard appeals by 14 calendar days. And both regulations require either that the enrollee request the extension or that the health plan be able to demonstrate to the state, if it asks, that the extension was in the enrollee's interest. But the January final regulation required the health plan to "dispose of the grievance or resolve the appeal no later than the date on which the extension expires."[12] The proposed rule inexplicably eliminates this requirement, thus allowing indefinite extensions and no certainty of resolution. This undermines the guarantees of the internal appeals process provided for in the BBA.

> **Section 438.408** The health plan should be required to resolve the appeal or dispose of the grievance no later than the date on which the extension expires.

C. Expedited Appeals

Many emergency health conditions are so serious that the time necessary to wait for a standard appeal could endanger an enrollee's health. Both the January final rule and the proposed rule create an expedited appeals process to address these situations. The process for expedited appeals and grievances in the proposed rule, however, is inadequate. It does not protect enrollees in emergency situations because it gives health plans an undue amount of time to respond to the emergency and an undue degree of latitude in deciding how much time the response will take.

1. Challenging the Denial of a Request to Expedite an Appeal (§ 438.410)

The proposed rule keeps many of the requirements about how to decide if an appeal should be expedited. Both regulations allow enrollees to request that their appeal be expedited. Both regulations require the health plan to expedite an appeal if either: (1) the health plan decides that "taking the time for a standard resolution could seriously jeopardize the enrollee's" life or health; or (2) the provider makes a request on the enrollee's behalf indicating that delay would jeopardize the enrollee's

[12] Jan. Final Rule § 438.408(d)(2)(ii).

life or health.[13] And both regulations require that if the health plan denies the request, that it must inform the enrollee of that denial.

The proposed rule, however, deletes notice to enrollees that their appeal would be expedited if a provider files a letter supporting the request. It is important to note that the proposed rule maintains the requirement that health plans expedite the appeal if providers support the request.[14] The only difference is that, under the proposed rule, there is no requirement that health plans tell enrollees about this requirement. Again, this amendment was not explained and is not justified.

> **Section 438.410** Health plans should be required to inform the enrollee that their appeal will be expedited if the provider submits a letter of support for the request.

In addition, the proposed rule removes enrollees' ability to file an effective grievance when their request to expedite is denied. The January final rule recognized the importance of being able to challenge a decision not to expedite an appeal. It created an expedited grievance procedure that required health plans to resolve the grievance within 72 hours of filing.[15] The proposed rule deletes this requirement.

The proposed regulations specifically acknowledge that an enrollee can file a standard grievance based on the denial to expedite; indeed, the proposed regulations require special handling of these grievances.[16] But a standard grievance is meaningless because under the proposed regulations, health plans may have up to 90 days to respond to them. By that time, the appeal should have been resolved under

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[13]Jan. Final Rule § 438.410(c)(2); Proposed Rule § 438.410(a).

[14]The proposed rule is not as clear about the requirement as the January final rule was. The January final rule directly required an expedited appeals process by stating that the health plan must "provide for an expedited appeal" if the provider indicated that taking the time for a standard resolution would seriously jeopardize the enrollee's health. The proposed rule obfuscates this requirement because instead of saying the health plan must provide for an expedited appeal, the rule states that the health plan must "establish and maintain an expedited review process for appeals" when the provider supports it.

[15]Jan. Final Rule § 438.408(c)(2).

[16]Section 438.406(a)(3)(ii)(B) of the proposed rule requires the health plan to ensure that a health professional with clinical expertise be involved in handling any "grievance regarding denial of expedited resolution of an appeal."

the standard timeframe. Enrollees should be able to challenge what is otherwise a unilateral decision by health plans about whether to expedite an appeal. The proposed rule eliminates this right without explanation.

> **Section 438.408** A provision should be added to allow for an expedited disposition of grievances on a denial of a request to expedite an appeal

Finally, the proposed rule deletes the requirement that the health plan inform enrollees of their right to file a grievance.[17] This deletion is of course understandable if the regulation does not contain an expedited grievance procedure. But, as discussed above, the rule should allow for expedited grievances when the enrollee's request to expedite an appeal is denied, and the health plan should be required to tell the enrollee about them.

> **Section 438.410** Health plans should be required to inform enrollees of their right to file a grievance if their request to expedite an appeal is denied.

2. Timeframe for resolution of expedited appeals (§ 438.408)

The proposed rule significantly expands the time that health plans have to respond to an expedited appeal. Under the January final rule, health plans had 72 hours to respond to an expedited appeal. This timeframe is practical. If an appeal is moving forward on an expedited basis, it is because health plans or providers have decided that the time for a standard resolution could "seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function." The 72 hour standard has already been supported by President Bush in H.R. 2563. This standard is also consistent with Medicare, which requires health plans participating in Medicare+Choice to decided expedited appeals within 72 hours.[18]

The proposed rule, however, arbitrarily and without explanation, amended this timeframe to allow the health plan up to 3 working days to resolve an expedited

[17] Jan. Final Rule § 438.410(d)(2)(i)(A).

[18] *See*, 42 C.F.R. § 422.572.

appeal.[19] In other words, enrollees who file an expedited appeal Wednesday afternoon may not receive a resolution until the following Monday, five days later.

Weekends are times of rest, and it is understandable that many requirements do not count Saturday and Sunday as days on which work should be done. But a condition that could seriously jeopardize someone's health makes no distinction between a workday and a weekend and neither should the appeals process designed to address that condition.

> **Section 438.408** Health plans should be required to respond to expedited appeals within 72 hours.

3. Extension of Timeframe of Expedited Appeals and Grievances (§ 438.408)

The January final rule allowed health plans to extend the deadline for an expedited appeal only at the enrollees' request. The proposed rule, however, allows health plans to extend the timeframe for an expedited appeal for 14 calendar days even if enrollees have not requested it and even without asking the enrollee. The only check on the extension is that if the state requests information about the delay, health plans must demonstrate that the delay is in the interest of the enrollee. But because the state has no mechanism to know that health plans have given themselves an extension, this is an empty mechanism. Accordingly, even where the delay could seriously jeopardize the enrollee's health, the health plan can extend the already lengthy three working days by an additional 14 calendar days with no recourse to the enrollee or notice to the state. In addition, as discussed above, the health plan could grant itself indefinite extensions because the proposed rule does not require health plans to resolve the appeal after the first extension.

> **Section 438.408** The expedited resolution should only be extended if the enrollee requests it.

The January final rule also contained a provision forbidding the extension of grievances based on a denial to expedite an appeal. The proposed rule does not allow for expedited grievances and so, accordingly, does not provide for extensions for expedited grievances. As discussed above, however, the regulation should allow

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[19]The proposed regulation did retain the requirement that the health plan resolve each appeal "as expeditiously as the enrollee's health conditions require." § 438.408(a). But this requirement provides little comfort because it is amorphous, left to the plan to interpret, and therefore difficult to enforce.

for expedited grievances.

> **Section 438.408** The regulation should prevent the health plan from extending the timeframe to dispose of an expedited grievance.

4. Action Following the Denial of a Request for Expedited Resolution (§ 438.410)

If a health plan denies the request to expedite an appeal, both the January final rule and proposed rule would require the health plan to transfer the appeal to the standard timeframe. The January final rule, however, contained a crucial protection that the proposed regulations delete. The January final rule required the health plan to start the clock on the standard appeal timeframe "as of the day it received the request for expedited resolution." The proposed regulation makes no mention of when the clock on the standard appeal must begin. As a result, the health plan's system could take two weeks to officially transfer the appeal, and the appeal may be delayed during that entire time period. The arbitrary result is that enrollees who seek expedited appeals may have to wait the longest for a resolution.

> **Section 438.410** If the enrollee's request for an expedited appeal is denied, the health plan should be required to transfer the appeal to the standard timeframe as of the day that the request to expedite was received.

D. Structure of Grievance and Appeal Systems

1. Delay of Care/Response not Reviewable (§ 438.400)

Both regulations establish parameters under which an enrollee can file an appeal. Under both regulations, an enrollee is allowed to appeal an "action" by the health plan. Under the January final rule, an "action" was defined as a denial of services, reduction of services, denial of payment, denial of a rural enrollees' request to obtain services outside the entity, *the failure to furnish services in a timely manner, the failure to resolve an appeal in a timely manner, or the denial of an enrollees' request to disenroll*.

While the proposed rule retains many of these same definitions, it does not define either the failure to furnish services in a timely manner or the failure to

resolve an appeal in a timely fashion as an "action."[20] As a result, if a health plan delays furnishing services, the health plan has taken no "action" and the enrollee has no right to appeal. A health plan can avoid the formal appeal process simply by not doing anything. Similarly, if a health plan never responds to an appeal, the enrollee will have no right to a state fair hearing in states that require exhaustion of remedies with the health plan. Again, in these states, a health plan could avoid review by simply never responding to the enrollee's appeal.

These amendments are both unexplained and unjustified and have an extremely serious impact. A delay in care or treatment can be as detrimental to an enrollee's health as a formal denial of care or treatment. It is arbitrary to allow the appeal of one but not to allow the appeal of the other. In fact, the proposed regulations create a perverse incentive to simply delay or not provide services.

In addition to being bad policy, the proposed regulations also violate the Act. Section 1902(a)(3) requires the state plan to provide for a state fair hearing to an individual whose request for services is "not acted upon with reasonable promptness." In states that require the enrollee to exhaust remedies with the health plan before allowing access to a state fair hearing, the enrollee may never have access to the state fair hearing when care has been delayed. In those states, the inability to appeal a delay in service, or a delay in responding to an appeal, would result in an inability to access the state fair hearing. As a result, an enrollees' statutory right to a state fair hearing for delay in service would be denied.

> **Section 438.400** The definition of "action" should include the failure to provide service in a timely manner and the failure to respond to an appeal in a timely manner.

2. Structure of the Grievance System (§ 438.402)

Section 1932(b)(4) requires health plans to establish an internal grievance system. In implementing this requirement, the January final rule created general requirements for such systems. It required, for instance, that the health plan base its grievance and appeals process on written policies, and that it obtain the state's approval of those policies.[21] It also required the health plan to accept grievance and appeals from the enrollees' representative, and to provide the enrollee or their

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[20]The proposed rule also deletes from the definition of action, the denial of an enrollee's request for disenrollment. In addition, the regulation contains an "or" after the last definition, but nothing follows the word "or."

[21]Jan. Final Rule § 438.402(b).

representative all required notices and information.[22]

The proposed regulation, without explanation, deleted this entire subsection. It proposes nothing in its place choosing instead to leave the structure of the grievance and appeals section entirely within the discretion of the state. Such wide latitude is insufficient to guarantee that an enrollee's statutory right to a grievance system required by § 1932(b)(4) will be truly implemented. Minimal protections for violations short of denial should be provided.

> **Section 438.402** Provisions in the January final rule regarding general requirements for the grievance system should be added to the regulation.

3. Requirements in Handling Grievances (§ 438.406)

Both regulations establish requirements that health plans must follow in handling grievances and appeals. The January final rule had seven requirements including a requirement that the health plans give enrollees assistance in completing forms and acknowledge the receipt of each grievance and appeal. The proposed regulation retains three of these requirements exactly as they were written in the January final rule, but it deletes four of them without explanation.

The four requirements that the proposed rule deletes are that health plans: (1) have an adequately staffed office that is designated as a central point for enrollees' issues; (2) establish an appeal process that meets the regulations; (3) ensure that enrollees' communications are properly classified as grievances or appeals; and (4) ensure that each grievance or appeal is timely transmitted and disposed of within the proper timeframe.

All four of the deleted provisions were designed to ensure an efficient and well managed handling of grievances. They should all be reinstated. One provision in particular stands out as an especially important requirement: that the health plan properly classify the enrollee's communication as a grievance or an appeal. It is quite likely that an enrollee will not know whether they are trying to file a grievance or an appeal; it is a distinction that can quite easily be lost on a layperson. Failing to require health plans to properly classify complaints will result in misfiled complaints that may in turn result in the enrollee not receiving the hearing (and potentially the care) to which they are entitled under the BBA. Thus, this failure to ensure proper filing violates the Act.

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[22] *Id.*

Section 438.408 The January final rule regarding handling of grievances should be replaced.

4. No Requirement that Appeals be Automatically Forwarded to State (§ 438.408)

The January final rule required the health plan to automatically forward any expedited appeal that had been decided against the enrollee, or that had not been decided in the proper timeframe, to the state for review. This is a reasonable requirement. Without automatic forwarding, a significant time delay is created between the appeal and the state hearing. This time delay is especially problematic for vulnerable enrollees who are already in extremis. Moreover, this requirement is consistent with Medicare+Choice regulations that require the health plan to automatically forward adverse decisions of expedited cases to an outside entity for review.[23]

The proposed regulations delete this requirement. In the preamble, the Department states that it rejected the option of forwarding the appeals because it is burdensome.[24] This response is not sufficient. The question is not whether something is burdensome, the question is whether the benefits to be derived from requiring forwarding are worth the burden. In this instance, they are. In the case of expedited appeals, the enrollee's health could be in serious jeopardy. Timing is essential and automatic forwarding will provide the necessary speed to the process. The Department's explanation for why this provision was deleted does not withstand scrutiny.

Section 438.408 The regulations should require the health plan to forward to the state any expedited appeals that were not decided wholly within the enrollee's favor or that were not decided within the required timeframe.

5. No State Review of Quality of Care Grievance

Both regulations create a system for grievances in addition to appeals. But the January final rule created two types of grievances. The first was a normal grievance that an enrollee could file whenever they were dissatisfied with any

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[23] *See*, 42 C.F.R. § 422.590(d)(5).

[24] 66 Fed. Reg. at 43,640.

matter.[25] The second was a quality of care grievance, which was a grievance the enrollee could file if they believed any aspect of their care was substandard and could have caused them harm.[26] The January final rule recognized that such situations were deserving of enhanced review. Accordingly, the regulations allowed for state review of quality of care grievances if the enrollee was not satisfied with the resolution of the grievance.[27] The regulations also required the health plan to collaborate with the state to dispose of a grievance where the state considered the health plan's response to be inadequate.[28]

The proposed rule deletes all references to quality of care grievances, again without explanation and without justification. Substandard care could harm an enrollee, but if the only option were to file a grievance, they would be unable to get to the state or outside of the health plan's range. All of the references to quality of care grievances should be replaced.

Section 438.400 The regulations should define a quality of care grievance independent of the regular grievance.

Section 438.402 Health plans should be required to refer to the state any quality of care grievance with which enrollees are dissatisfied.

Section 438.408 Health plans should be required to collaborate with the state to dispose of grievances if the state considers the health plan's response to be insufficient.

E. State Fair Hearing

1. Timing Requirements (§ 438.408)

The January final rule established timeframes for the state fair hearing process that accounted for the time enrollees would spend in health plans' appeal process and also for enrollees' health.

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[25]Jan. Final Rule § 438.400(b).

[26]Jan Final Rule § 438.408(b).

[27]Jan Final Rule § 438.402(b)(8).

[28]Jan. Final Rule § 438.408(h).

The regulations required the state fair hearing process to be completed within 90 days minus the number of days taken by the health plan to resolve the internal appeal.[29] This requirement is in keeping with the spirit of the state fair hearing process, which requires that an enrollee's case be resolved within 90 days of the appeal. This requirement is also consistent with what Medicaid enrollees under fee for service are provided. Enrollees in managed care should not be forced to wait longer than 90 days simply because health plans have added an additional layer of review. But the proposed regulations delete any requirements regarding when a state fair hearing needs to be completed. As a result, enrollees who file appeals with health plans – as some states require them to do prior to seeking review through a state fair hearing – will wait for the resolution from the health plan and then be required to wait an additional 90 days on top of that time before the state is required to resolve the state fair hearing.[30]

> **Section 438.408** The state should be required to resolve the enrollee's state fair hearing within 90 days of receiving the request minus the number of days the health plan took to resolve the enrollee's appeal.

The January final rule also contained an expedited timeframe for state fair hearing requests based on an adverse decision of an expedited appeal. The regulation required the state to resolve the request "as expeditiously as the enrollee's health requires, but no later than 72 hours after the receipt of a fair hearing request."[31] As mentioned above, the proposed regulation deletes any reference to timeframes for resolution of the state fair hearing. As a result, an enrollee who has a serious health condition may be required to wait 90 days for the resolution of the state fair hearing. This amendment is unacceptable.

> **Section 438.408** The state should be required to resolve requests for state fair hearings based on an adverse decision of an expedited appeal as expeditiously as the enrollee's health requires but at least within 72 hours.

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[29]Jan. Final Rule § 438.408(j)(3)(i).

[30]42 C.F.R. § 431.244(f) allows the state 90 days to resolve a state fair hearing request.

[31]Jan. Final Rule § 438.408(j)(3)(ii).

F. Continuation of Benefits While Appeal or State Fair Hearing is Pending

1. Reinstatement of Benefits While State Fair Hearing is Pending (§ 438.420)

The January regulation required health plans to reinstate enrollees' benefits, as long as enrollees met the requirements of 42 C.F.R. § 431.231.[32] Section 431.231 provides, in part, that enrollees' benefits must be reinstated if the action to terminate was done without adhering to advance notice requirements, as long as the enrollee files a timely appeal.

The proposed rule inexplicably eliminates the requirement that the health plan reinstate the enrollee's benefits under the circumstances provided for under §432.231. This change eliminates the automatic continuation, or reinstatement, of benefits even where the health plan terminated benefits without complying with the advance notice requirements. This effectively rewards plans for not complying with advance notice requirements and puts additional burdens on enrollees to affirmatively request the continuation of benefits.

> **Section 438.420** The health plan should be required to reinstate benefits under the circumstances specified in 42 C.F.R. § 431.231.

2. Continuation of Benefits Pending Appeal

Both the January final rule and the proposed rule require the health plan to continue the enrollee's benefits pending an appeal if the enrollee requests that benefits be continued. However, the proposed regulation is worded poorly. It states that if the plan has decided an appeal against the enrollee, it can discontinue benefits "unless the enrollee *has requested* a State fair hearing." (emphasis added) By putting the requirement in the present perfect tense ("*has requested*"), the regulation requires the enrollee to have requested a state fair hearing before the appeal is even resolved, or at the very least, at the moment that it is resolved, or risk losing their benefits.

> **Section 438.420** The regulation should be amended to allow the enrollee sufficient time to file for a state fair hearing review before their benefits are discontinued following an adverse appeal decision.

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[32] Jan. Final Rule § 438.420(c).

G. Information, Record Keeping, and Reporting Requirements

1. Record keeping and Reporting Requirements § 438.416

Section 1932(c)(1)(A)(ii) of the Act requires states to undertake quality assessment and improvement measures including examining the grievance procedures of health plans. The January final rule implemented this requirement by requiring health plans to maintain records that would be the minimum necessary to adequately evaluate plans' response to grievances. The regulations required the plans to maintain logs of grievances and appeals, to track their progress through the system, to retain records of the grievances and appeals, and to analyze the records and report to the state on the analysis at least once a year.

The proposed regulation, without any explanation, deletes all of these requirements and puts in their place the standardless provision that the State require the health plan to "maintain records of grievances and appeals" and "review the information as part of the state quality strategy." The lack of definitions for what records the health plan must maintain is inadequate to guarantee that useful information will be kept. For instance, a health plan could conceivably be in compliance with this regulation if it kept a count only of how many grievances and appeals it received. Such information would be virtually useless in trying to assess quality. Thus, under the proposed regulation, the state would be unable to complete its statutory duty to assess the quality of the system. The proposed regulation is bad policy .

In addition, the proposed rule violates other parts of the Act as well. Section 1932(c)(2)(A)(i) requires health plans to undertake an annual review of quality outcomes and timelines of the provision of services. But the proposed rule does not require health plans to maintain the data necessary for this review.

Section 438.416 Health plans should be required to comply with the record-keeping requirements of the January final rule.

2. Information about the Grievance System § 438.414

The January final rule required health plans to provide aggregate information about their grievance systems upon request. The proposed regulation deletes this requirement entirely. As a result, vital public accountability and monitoring will be seriously hampered.

Section 438.414 Health plans should be required to provide aggregate information about their grievance and appeals to enrollees and to the general public.

III. ADDITIONAL PROTECTIONS FOR SPECIAL POPULATIONS MUST BE ADDED

A. Individuals with Special Health Care Needs

More than 5 million Medicaid enrollees have a physical or mental disability and more than 4 million beneficiaries are older than age 65.[33] Medicaid covers hundreds of thousands of children who live in foster care, and many thousands of homeless men, women, and children.

Because Medicaid is a safety net for America's most vulnerable citizens, the Balanced Budget Act specifically asked HHS to evaluate

> the safeguards (if any) that may be needed to ensure that the health care needs of individuals with special health care needs and chronic conditions who are enrolled with Medicaid managed care organizations are adequately met.[34]

In November 2000, after an extensive consensus-oriented and evidence-based review of available data, HHS issued its report entitled *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*. The January final rule adopted many of its recommended protections to assure high quality medical services for such individuals, at minimal administrative burden to states.

Without explanation, the proposed rule arbitrarily deletes virtually all of these important protections.

1. Definition of Special Health Care Needs (§ 438.208)

The first step in protecting vulnerable patients in managed care is to identify them amidst all of the enrollees. According to *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, "For many . . . safeguards to be implemented, the State must identify individuals with such needs to

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[33]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

[34]Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4705(c)(2).

the MCO at the time of enrollment, or the MCOs must identify them soon after enrollment."[35]

A minimum standard national definition allows for comparison between states and would allow HHS to identify areas in need of additional resources and national attention. As the President's Commission on Consumer Protection and Quality in the Health Care Industry found, "[e]xisting data sets used in quality measurement often lack the variables that facilitate identification of vulnerable populations for quality assessment purposes. Routine availability of such information would make it feasible to undertake monitoring of vulnerable persons as part of quality measurement initiatives more frequently."[36] Similarly, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* found, "The need for tested and validated tools is increasingly being recognized by experts who care for individuals with special health care needs."[37]

To address this issue, the January final rule set a minimum definition of "individuals with special health care needs" that included: (1) children and adults receiving SSI benefits; (2) children in foster care; (3) enrollees over the age of 65; (4) children under age 2; (5) pregnant women; (6) other enrollees as defined by the state or HHS. Inclusion of each of these groups is well justified. SSI benefits are only given to elderly or disabled individuals and are likely to depend on medical services. Children in foster care have a wide variety of special health needs.[38] Enrollees over the age of 65 in Medicaid are at high risk for a host of medical conditions. Children under age 2 require attention to their immunization status. Pregnant women have unique needs that are critical to the health of the woman and her future child. Significantly, all these groups are eligibility classes, easily identifiable to state Medicaid programs through their administrative databases at minimal expense.

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[35]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

[36]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans* (1998).

[37]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

[38]*See, e.g.*, B. Zima, R. Bussing, X. Yang, T. Belin, *Help-Seeking Steps and Service Use for Children in Foster Care*, Journal of Behavioral Health Services Research, 271-85 (August 2000).

Without explanation, the proposed rule arbitrarily eliminates all minimum requirements for a definition of individuals with special health care needs, leaving the wording up to each state. A state could pick a narrow definition of "special health care needs" that ignores key populations. This single provision undermines many subsequent protections for millions of vulnerable individuals. It also violates the Balanced Budget Act in at least two regards.

First, the regulation may § 1932(a)(2)(A) of the Act because it fails to protect populations identified by Congress as needing extra protections. Section 1932(a)(2)(A) exempts five groups from being forced into managed care arrangements. It is reasonable to assume that these groups also should be specially protected within such arrangements, but they are not in the proposed rule.

Second, the lack of a minimum definition violates the BBA's requirement to monitor those with special health care needs. Section 1932(c)(1)(A)(iii) requires the state to develop procedures to monitor and evaluate the quality of care given to "the full spectrum of populations enrolled under a contract." Yet, without a definition of who is included, it is impossible to monitor quality for individuals with special health care needs.

> **Section 438.208**: A provision should be added defining a minimum group of individuals with special health care needs, to include (1) children and adults receiving SSI benefits; (2) children in foster care; (3) enrollees over the age of 65; (4) children under age 2; (5) pregnant women; (6) other enrollees as defined by the state or HHS.

2. Identification and Screening (§ 438.208)

The proposed rule requires states to "implement mechanisms for the identification and assessment of persons with special health care needs as defined by the state." On one hand, these words seem to recognize that identifying and assessing individuals at high risk for inadequate care is essential to protecting them. Indeed, as *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* noted, "Assessment of needs is generally regarded as an essential component of providing appropriate care to enrollees with complex health conditions."[39]

Unfortunately, the proposed rule's language on this point is so vague as to be meaningless. First, as noted above, the state can fail to designate key populations

[39]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, 53 (2000).

as having special health care needs. Second, the assessment process and timetable is entirely standardless. Even a former premature baby with profound respiratory difficulties and neurological impairment is not guaranteed of screening under the proposed rule.

By contrast, the January final rule required that plans make their best effort to screen enrollees within 30 days from the time of enrollment and to provide a comprehensive health assessment within 30 days for any enrollees identified as having special health care needs. A child with a disability or chronic illness would have to be contacted and screened within 30 days, with a comprehensive health evaluation soon to follow. Similarly the Medicare+Choice regulations require a "best effort" attempt at an assessment within 30 days of enrollment.[40]

> **Section 438.208**: As in the January final rule, a provision should be added to give health plans 30 days to screen individuals identified by the state as having special health care needs, and 30 days to provide a comprehensive health assessment to any enrollees found to have special health care needs.

3. Transition Plans (§ 438.62)

It is widely recognized that the transition to managed care plans can be a difficult experience for enrollees with chronic medical conditions. In *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, HHS found:

> Individuals are most vulnerable during critical transitions, such as admission or discharge from a hospital or nursing facility, entrance to school, the death of a spouse or parent, change in provider, the initiation of a new treatment, or enrollment into managed care.[41]

During the transition to a managed care plan, the individuals may lose providers they know well or need new approvals for long-received services.

Because so much is at stake during this transition, the January final rule assured that states "must have in effect a mechanism to ensure continued access to services" during the transition to managed care for enrollees with ongoing chronic

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[40]42 C.F.R. § 422.112(b)(4)(i).

[41]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

medical conditions. This provision was developed based on recommendations from the President's Commission on Consumer Protection and Quality in the Health Care Industry and *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*.[42] Yet the proposed rule arbitrarily eliminates this important requirement without any explanation, exposing enrollees to substantial risk.

> **Section 438.62**: A provision should be added to require states to have a mechanism to ensure continued access to services for individuals with special health care needs and ongoing chronic medical conditions during the transition to managed care.

4. Treatment Plans (§ 438.208)

The standard of care for individuals with special health care needs revolves around the development of a comprehensive treatment plan.[43] The January final rule required such a plan to be developed for all enrollees determined to have special health care needs; the plan, in turn, had to guarantee standing referrals or adequate number of direct visits to specialists and assure adequate coordination of care. Simiarly, the Medicare+Choice regulations require a treatment plan for all enrollees with serious medical conditions.[44] The proposed rule, however, leaves the development of a treatment plan entirely to the discretion of the managed care plan.

As a result, under the proposed rule, individuals with special health care needs have no right to a treatment plan or to any protections that such a treatment plan might offer. The result is arbitrary and inconsistent with BBA's protection of individuals with special health care needs and exposes vulnerable patients to inadequate care.

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[42] *Id.*

[43] Committee on Children with Disabilities of American Academy of Pediatrics, *Care Coordination: Integrating Health and Related Systems of Care for Children With Special Health Care Needs*, Pediatrics, 978-981 (October 1999) ("[C]are coordination . . . is the key to efficient management of the many complex issues surrounding the care of children with special health care needs within the context of the medical home.") ("The care coordinator has the primary responsibility for the child's treatment plan.").

[44] 42 C.F.R. § 422.112(a)(4).

Section 438.208: A provision should be added to require that managed care plans implement treatment plans for all individuals with special health care needs. Such treatment plans should, at a minimum, be appropriate to the standard of care for the condition and needs identified, be updated periodically, specify a standing referral or adequate number of direct visits to specialists, assure adequate coordination of care, be developed with enrollee participation, and ensure reassessment of each enrollee as his/her health condition requires.

5. Education of Providers (§ 438.68)

The January final rule required that the state have procedures to educate health plans and subcontracting providers about how to best provide care for individuals with special health care needs. Such education was considered essential by HHS in *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*. The report found:

> MCOs and their providers need to be educated about the 'special health care needs' of enrollees, the other systems of care from which enrollees receive services, and the unique aspects of treatment of individuals with special health care needs. These were the findings of a HCFA-commissioned review of literature and 51 in-depth interviews with national organizations and agencies, state agencies, advocacy groups, community based organizations, MCOs and health providers in Tennessee and Colorado.[45]

Despite this compelling evidence, the proposed rule arbitrarily eliminates all reference to educating providers on special health care needs, again without any explanation. In Section 438.10, the proposed rule compounds this failure by denying individuals the right to learn about the training of physicians in the health plan. As a result, vulnerable patients who need specialized attention may find themselves cared for by unprepared clinicians – and not even know it.

Section 438.68: A provision should be added to require states to develop procedures to educate health plans and providers about care for individuals with special health care needs.

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[45]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

6. Assistance for Communication (§ 438.102)

The January final rule required that plans "ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options." This provision is especially important for those enrollees whose disabilities affect their ability to see or hear. The President's Commission on Consumer Protection and Quality in the Healthcare Industry emphatically endorsed this right. The Commission said that plans must "ensure that persons with disabilities have effective communications with members of the health system,"[46] even if this requires clinics and offices "to provide auxiliary aids and services and remove communication barriers." Similarly, in *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, HHS found that "information strategies for populations should recognize that the existence of disabilities can impair receipt and understanding of information."[47] The Medicare+Choice regulations require that, "[h]ealth care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options."[48]

The proposed rule, however, drops this provision arbitrarily and without explanation. As a result, individuals with disabilities may be without even a most basic right – the ability to express wishes about medical treatment.

> **Section 438.102**: A provision should be added to require plans to take steps to ensure that health care professionals ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

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[46]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

[47]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

[48]42 C.F.R. § 422.206(a)(2).

7. Network Adequacy (§ 438.206)

The proposed rule, unlike the January final rule, has no specific provision that plans must develop a provider network adequate to serve pregnant women, children and individuals with special health care needs. As recognized in *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, network adequacy is essential for such individuals. The report noted:

> Individuals who have special health care needs also require access to a wide range of specialty health services, including specialty physician and dental services; occupational, physical and speech therapy; and hospital services...For example, an individual suffering from Alzheimer's disease could need access to services from geriatricians, geriatric psychiatrists, neurologists, nurses and social workers...Young children with developmental delays or with diagnosed conditions that have a strong chance of resulting in developmental delays might need services that include physical therapy, occupational therapy, speech-language pathology and services, audiology services and respiratory therapy.[49]

Without a specific provision on network adequacy for patients with special health care needs, plans may interpret a general provision on network adequacy to require only an overall survey of members, rather than a targeted assessment of the needs of the most vulnerable and ill patients. This would substantially compromise health care for this key group.

> **Section 438.206**: A provision should be added to require health plan networks to develop networks adequate to provide care to individuals with special health care needs.

8. Physical Accessibility of Offices (§ 438.10)

It is tautological that individuals with disabilities need to find physicians and health practitioners whose offices are physically accessible for them. The January final rule required that enrollees have a right to information on "physical accessibility" of health care facilities. This rule made sense: Providing such information is of little expense to the plans. In the preamble to the proposed rule, the Administration also states that enrollees should be able to obtain information on "physical accessibility" of doctors' offices and other parts of health plans. However,

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[49]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

such a provision is not part of the proposed rule. The omission of this provision from the proposed rule needlessly forces patients to contact each and every possible physician, laboratory, and other health facility to ask about accessibility and could delay lifesaving care in the event of an emergency.

> **Section 438.10**: A provision should be added to give enrollees the right to information on requirements for accessing services to which they are entitled under the contract, including factors such as physical accessibility and non-English languages spoken.

B. Racial and Ethnic Minorities (§ 438.206)

As the 21st century begins, Medicaid must work to provide quality care to individuals of every race and ethnicity. It has recently been recognized, however, that many providers are not trained to take care of individuals with different cultural and ethnic backgrounds from themselves.[50]

To rectify this problem, the U.S. Department of Health and Human Services Office of Minority Health (OMH) has taken the lead in promoting "cultural competence." The office has recently promoted national standards on Culturally and Linguistically Appropriate Health Care Services (CLAS). Standard 5 states that health care organizations should "[r]equire and arrange for ongoing education and training for administrative, clinical, and support staff in culturally and linguistically competent service delivery."[51]

These skills are clinically important. As the President's Commission on Consumer Protection and Quality in the Health Care Industry found,

> Significant differences in treatment have been documented by race, ethnicity, and sex that are not explained by other demographic differences, insurance status, clinical factors, or provider characteristics. For instance, African-Americans with colorectal cancer have been found to be treated less aggressively than their white counterparts . . . A number of studies have consistently demonstrated that African Americans are about half as likely to

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[50]Resources for Cross Cultural Health Care, *Assuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcomes-Focused Research Agenda*, http://www.omhrc.gov/clas/po.htm (Accessed September 29, 2001).

[51]Office of Minority Health, *Assuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcomes-Focused Research Agenda,* http://www.omhrc.gov/clas/ds.htm (Accessed September 29, 2001).

> receive interventional therapy for coronary artery disease...Differences between Latinos and non-Hispanic whites in the use of invasive cardiac procedures also have been documented.[52]

In Section 438.102, the January final rule embraced the OMH standard by requiring that health plans assist health professionals in furnishing "information about treatment options...in a culturally competent manner." Medicare+Choice regulations also require that services "are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds."[53] The proposed rule, however, drops this provision arbitrarily and without explanation.

Under the proposed rule, plans must only participate in state efforts to promote "the delivery of services in a culturally competent manner." What the "state efforts" must be is not defined. Moreover, states are not required to have any efforts at all. As a result, there is actually no requirement in the regulations for any support of culturally competent care. The lack of such a provision will undermine care for ethnic and racial minorities.

> **Section 438.206:** A provision should be added to require plans to take steps to improve the cultural competence of care provided by health professionals.

C. Homeless and Migrant Workers (§ 438.56)

The January final rule allowed homeless individuals and migrant workers who were enrolled by default into particular managed care plans to disenroll and choose a plan anew once in contact with the state Medicaid program. This provision was deleted from the proposed rule without any explanation. Whether such individuals receive any protections in this regard is left entirely to states.

This deletion is profoundly unfair to those individuals who may have developed close affiliations with particular health centers, mobile health teams, or physicians. Under the terms of the proposed rule, such individuals may have no

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[52]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans* (1998).

[53]42 C.F.R. § 422.112(a)(9).

recourse if assigned to health plans that do not contract with those who can care for them. As written, the proposed rule arbitrarily punishes people for not having a fixed address.

> **Section 438.56**: A provision should be added to allow homeless individuals and migrant workers to disenroll within 60 days of learning of any assignment to a managed care plan.

D. Residents of Rural Areas (§ 438.52)

Under the BBA, states may limit enrollees to one MCO in rural areas as long as individuals can obtain out-of-network coverage in "appropriate" circumstances.[54] The January final rule defined one of these circumstances as a patient's main source of care did not join the MCO network. In this circumstance, the January final rule allowed the enrollee to stay with the out-of-network provider "as long as the provider continues to be the main source of the service" to the enrollee.

In contrast, the proposed regulation amends this section to require the provider to become a part of the network within 60 days. If the provider chooses not to become a part of the network, or fails to join within 60 days, the enrollee must switch to a provider in the network.

This requirement is bad policy. For instance, as the January regulation explained, a woman in a high risk pregnancy may need to stay with her provider. The President's Commission on Consumer Protection and Quality in the Healthcare Industry recommended at least 90 days of transition care or through the end of postpartum care.[55] The Commission noted that "sudden interruption of care can compromise the quality of care and patient outcomes."[56] Similarly, H.R. 2563 as passed by the House, which President Bush supports, contains a provision permitting transitional care for up to 90 days or to the end of pregnancy.[57] These provisions applied even in the presence of multiple plans. By requiring enrollees to switch providers after 60 days, the provision undermines care for pregnant women in

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[54]Section 1932(a)(3)(B) of the Act.

[55]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

[56]*Id.*

[57]H.R. 2563, Section 117(b).

high-risk pregnancies and jeopardizes many disabled individuals who have longstanding relationships with local physicians.

This provision also violates the Balanced Budget Act of 1997. As mentioned above, in rural areas, managed care entities are required to permit an enrollee to "obtain . . . assistance from any other provider in appropriate circumstances."[58] When an enrollee, such as a woman with a high-risk pregnancy or an individual with an acute life-threatening medical condition, is receiving most of her services from an established provider, it is an appropriate circumstance to let her continue to see this out-of-network provider. Accordingly denying the enrollee's ability to stay with that provider violates the BBA.

> **Section 438.52**: A provision should be added to allow rural residents forced into a sole MCO to continue to see their physicians out-of-network for at least 90 days or as long as an acute medical condition (e.g., pregnancy) persists. If there are no other local physicians, then out-of-network care should continue indefinitely.

IV. CHANGES ARE NEEDED TO IMPROVE HEALTH CARE QUALITY

Health care quality strategies are gaining momentum in order to reduce errors, foster evidence-based treatment, and assure optimal outcomes of medical care. Unfortunately, the proposed rule undermines key measures that support quality.

A. Performance measures (§ 438.240)

An entire field of medical research is devoted to assessing the performance of health plans on meaningful patient outcomes including survival, disability, and pain. In devising performance measures, plans should follow the path set out by this research. Plans should not be allowed to develop meaningless measures of performance – such as the numbers of prescriptions – that are designed from the start to show success.

The January final rule required that quality measures for performance projects be "objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and capable of measuring outcomes such as change in health status, functional status, and enrollee satisfaction, or valid

[58]Section 1932(a)(3)(B)(ii) of the Act.

proxies of these outcomes." This wording was virtually identical to provisions in the Medicare+Choice regulations.[59] The proposed rule, however, deletes all requirements beyond "objective." This change is per se arbitrary. As a result, plans are free to develop quality measures that may be irrelevant to patient care, and the quality initiatives may not protect patients at all.

> **Section 438.240**: Quality improvement initiatives should be measured according to standards set out in the January final rule.

B. Frequency of Reviews (§ 438.202)

While the proposed rule requires MCOs and PIHPs to have strategies for assessing and improving care, there is no requirement that states ever review these plans. (The January final rule required reviews at least every three years). Without such oversight, the quality strategies can be wholly inadequate.

> **Section 438.202**: A provision should be added to require states to review health plans' quality strategies at least once every three years.

C. Review standards (§ 438.210)

When reviewing requests for authorizations, plans should follow a reasonable standard of care. To promote this goal, the January final rule required that plans review requests for treatment using "written policies and procedures that reflect current standards of medical practice." The January final rule cited HIV guidelines as an example of such standards.

Inexplicably, and arbitrarily, the proposed rule drops the clause "that reflect current standards of medical practice" and deletes the example of HIV guidelines. Under the rule as proposed, plans are free to develop their own protocols that may conflict with professional standards for Medicaid enrollees. Evidence suggests that this is a real risk. As noted in *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*:

> Responses to a [National Alliance for the Mentally Ill] survey by nine of the largest managed behavioral health care organizations in the United States revealed that treatment guidelines for schizophrenia used by the behavioral health care organizations are out-of-date and do not mention the newest anti-

[59] 42 C.F.R. § 422.152(b)(7).

psychotic medication, or address the full range of care people with severe psychotic illness require.[60]

By allowing out-of-date guidelines that may actually systematize inadequate care, the provision thus offers nothing in the way of protection for enrollees.

> **Section 438.210**: A provision should be added to require that written policies and procedures on authorization of services reflect current standards of medical practice.

D. Credentialing (§ 438.214)

The January final rule required that plans, with certain exceptions, follow a credentialing procedure "which may be no less than the state requires for private MCOs."

Without explanation, the proposed rule deletes all specific credentialing and recredentialing requirements, stating only that plans must have written procedures for selecting physicians. This omission also differs from the Medicare+Choice rules, which set specific standards for credentialing and require recredentialing at least every two years.[61] The lack of minimum standards is an open door for states to allow plans to lower standards for doctors who see Medicaid patients. For example, a plan could recertify doctors in private plans every three years, but every ten years in Medicaid plans. A doctor with a string of cases of medical negligence by year five might be able to keep seeing Medicaid patients. This is the very opposite of a patient protection.

> **Section 438.214**: A provision should be added on credentialing that is consistent with the January final rule.

E. Data Certification from Subcontractors (§ 438.606)

Health plans may subcontract key functions – including mental health care – to other companies. The January final rule required that subcontractors certify data submitted to the health care plan. The proposed rule, however, deletes this provision.

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[60]Department of Health and Human Services, *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care* (2000).

[61]42 C.F.R. § 422.204.

If subcontractors are not subject to the same rules as the managed care plans, then plans can be set up solely for the purpose to subcontract all functions and thereby evade the rules. Such evasion violates § 1902(a)(4), which speaks to the proper and efficient operation of the plan.

> **Section 438.606**: A provision should be added that subcontractors must certify data submitted to the health plans.

V. INFORMATION REQUIREMENTS NEED IMPROVEMENT

A. Gag Rules (§ 438.10)

Unmentioned in the preamble is a subtle but critical change from the January final regulation in how managed care plans must handle "a counseling or referral service" which is not covered because of "moral or religious" objections. Such services typically include fertility and family planning services. In the January final rule, such plans were only obligated to provide information "about how and where to obtain information about the service." For example, if a patient asked about fertility services, such a health plan would merely have to refer him or her to the state Medicaid program for an answer.

The proposed rule, however, now states that managed care plans need not say a word about any service not covered because of "moral or religious" objections. Instead, the state is obligated to provide information about how to obtain such services.

There are two problems with this approach. First, it permits plans to create "gag rules" against physicians and other health providers, who can be barred from even discussing how to find information about certain services. Such gag rules were specifically opposed by the President's Commission on Consumer Protection and Quality in the Health Care Industry,[62] are barred in H.R. 2563, the patients' rights legislation that the President supports,[63] are prohibited in Medicare+Choice

[62]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

[63]H.R. 2563, § 131.

regulations,[64] and run counter to the doctor-patient relationship.[65]

The second problem is that the state's information provided to patients about such services may have been long discarded by the time patients actually need care. It may be then difficult to find the information through the state system (especially without a mechanism to obtain assistance, see below). Patients naturally will turn to their doctors or health plans for assistance; the plans now can bar physicians from even giving patients a number for more information.

This provision may also violate the BBA. Section 1932(b)(3)(A)(ii) requires health plans to inform enrollees about services not covered because of a moral objection. The proposed regulations, however, violate this requirement because health plans do not need to disclose this information when patients actually need to know it.

This "gag rule" policy undermines sensible access to covered services for Medicaid patients unfairly in day-to-day practice. Moreover, in an emergency, patients may fail to obtain necessary care, placing their lives at risk.

> **Section 438.10**: A provision should be added to require plans to refer patients to where they can get information about services not covered for "moral or religious" reasons.

[64] 42 C.F.R. § 422.206

[65] *Remove Gag Rules,* American Medical News (February 19, 1996).

B. Consumer information (§ 438.10)

Another core patient protection is access to information on the quality of health plans and providers. According to the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, consumers should have the right to receive information including "licensure, certification and accreditation status" and cost control methods of health plans; "education and board certification and recertification" and compensation methods of health professionals; and accreditation status of health care facilities.[66] According to the Commission, such information fosters improvements in "the performance of the health care system, as providers seek to enhance their quality...in order to be more attractive to value-seeking consumers."[67] Moreover, the Commission explained that "health plans, facilities and professionals have an ethical obligation to inform consumers about how their actions can affect the consumer's life and health."

Consistent with these rights, the preamble to the proposed rule states that "MCOs and PIHPs are also required to provide information upon request" regarding "licensure, certification, accreditation," "a summary of methods for compensating physicians," and "a description of procedures to control utilization and expenditures." However, while these topics were covered by 438.10 in the January final rule, they cannot be found anywhere in the proposed rule. They were arbitrarily deleted without explanation.

> **Section 438.10**: A provision should be added to require all health plans to provide, upon request, (1) information on licensure, certification and accreditation status of MCOs and health care facilities; (2) information on education, licensure, Board certification and recertification; (3) a description of cost-control procedures; (4) summary descriptions of methods of compensation for physicians; (6) information on the financial condition of the plan, including the most recent audit.

C. Comparison Data (§ 438.10)

Access to comparative information on health plans is essential to allow Medicaid patients to make informed choices. Yet the proposed rule exempts PIHPs

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[66]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

[67]*Id.*

and PAHPs from comparative charts to be distributed to all potential enrollees. This exemption, which was not present in the January final rule, will undermine true competition among plans.

> **Section 438.10**: The provisions on comparative information should include all prepaid health plans as well as MCOs and PCCMs.

D. Mechanism for Understanding Managed Care (§ 438.10)

The January final rule provided that every "State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program." This general provision would be satisfied by a consumer office at the state level to help Medicaid patients navigate through individual plan rules.

Such a mechanism was recommended by the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry, which noted that "some individuals, especially vulnerable individuals (e.g., the frail elderly, and individuals with disabilities, sensory impairment, chronic illnesses and limited education) may need assistance in interpreting information."[68] The Commission found that consumer assistance programs "inspire confidence," "provide a safety valve" and "foster collaboration." The Commission explained, "Even in the best of systems, there will be individuals who fall through the cracks. Assistance programs provide a resource that can help such individuals resolve problems quickly and efficiently."[69]

Similarly, in *Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*, HHS noted, "State staff familiar with cognitively impaired beneficiaries report that written materials are seldom helpful to this population; one-on-one education with the beneficiary and family is needed."[70]

Without explanation, the provision for consumer assistance was dropped in the proposed rule. State responsibilities are limited to providing information, but if patients have questions about this information, there may be no place for them to

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[68]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans* (1998).

[69]President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities* (1998).

[70]*Id.*

turn. Also deleted in the proposed rule is the requirement that states explain how to obtain additional information about health plans. These omissions must be rectified to protect vulnerable patients.

> **Section 438.10**: A provision should be added to require states to create a mechanism to handle questions about health plans from enrollees.

E. Information on Mental Health, Substance Abuse, and Drug Benefits (§ 438.10)

The January final rule specifically required plans to disclose information on mental health, substance abuse and prescription drug benefits. The proposed rule, however, only says that plans should provide information on "the amount, duration and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled." The preamble explains that "sufficient detail should be furnished to ensure that beneficiaries receive the services to which they are entitled, such as pharmaceuticals, mental health, and substance abuse services."

If the intent is for plans to disclose information on drug, mental health, and substance abuse benefits, then the proposed rule should explicitly include them in the regulation. H.R. 2563 as passed by the House, which President Bush supports, specifically requires disclosure of prescription drug benefits. Because the preamble does not necessarily have the force of law, these details should be included in the regulation itself.

> **Section 438.10**: A provision should be added requiring plans to disclose information on the amount, duration and scope of mental health, substance abuse, and drug benefits.

VI. OTHER PROVISIONS MUST BE ALTERED

A. Discrimination against Medicaid Patients (§ 438.206)

Without explanation, the proposed rule eliminates a provision from the January final rule prohibiting providers from "discriminat[ing] against Medicaid enrollees." As a result, there is nothing to stop a physician from having one standard of care for privately insured patients and another for Medicaid patients. Such a glaring omission from patient protections violates basic fairness, and the arbitrary

change from the final rule violates the Social Security Act. As the President's Commission on Consumer Protection and Quality in the Health Care Industry declared, "Consumers have the right to considerate, respectful care from all members of the health care system at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system." As part of this right, the Commission specifically opposed discrimination based on "source of payment," adding, "providers who agree to accept Medicaid beneficiaries must provide equal access, care, and waiting times to those patients. It will be vitally important for State and Federal agencies to closely monitor the provision of care to Medicaid beneficiaries as they move into new health plans."[71] The proposed rule's abdication of this role is unacceptable.

> **Section 438.206**: A provision should be added to prevent health professionals from discriminating against Medicaid enrollees.

B. Marketing Activities (§ 438.104)

In the BBA, Congress specifically acted to protect enrollees from marketing abuses. Section 1932(d)(2) provided detailed restrictions on marketing activities including prohibitions on cold-calling and door-to-door marketing of enrollment. The January final regulation implemented these restrictions by requiring managed care organizations to specify a method to prevent marketing plans from misleading, confusing or defrauding recipients. The proposed regulation retains this requirement – but creates an enormous loophole, effectively violating the Act.

The January final regulation defined marketing as "communication . . . to an enrollee or potential enrollee." This protects, as the BBA requires, all Medicaid recipients from marketing abuses. The proposed regulation, in contrast, defines marketing as "communication . . . to a Medicaid recipient who is not enrolled in that entity." The loophole created by this amendment is that current enrollees are not protected by any of the marketing restrictions in the regulation.

The exclusion makes no sense. Current enrollees can disenroll at least once a year and thus are a target audience for marketing from current plans. Under the proposed rule, states would not have to take any steps to police what plans tell enrollees to keep them in the plan. Moreover, the reverse problem is also a danger: Plans may lobby expensive current enrollees, who may have special health care needs, not to re-enroll– again without any regulatory oversight.

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[71] *Id.*

The BBA made no distinction between current and potential enrollees; it mandated protections from marketing period. By failing to protect current enrollees, the proposed rule violates the BBA.

> **Section 438.104**: The rule should not distinguish between potential enrollees and enrollees for marketing protections.

C. Network Adequacy (§ 438.206)

A common problem with managed care plans is that they expand too quickly. However, the proposed rule deletes a requirement from the January final rule that would require plans to demonstrate sufficient numbers of providers prior to an expansion. Such a provision already applies to Medicare+Choice plans.[72] This is a recipe for plans to attempt to gather market share, regardless of whether there are enough participating health providers. Any patients caught in the middle might have substantial trouble obtaining medical care.

The proposed rule may also violate provisions of the Act designed specifically to guard against such problems. Section 1902(a)(19) requires state plans to "provide safeguards" to assure that "services will be provided." In addition, § 1932(b)(5) requires the managed care organization to provide assurances that it has the "capacity to serve the expected enrollment." By deleting the requirement that the entity demonstrate capacity prior to expansion, the proposed rule could violate both provisions.

> **Section 438.206**: A provision should be added to require plans to demonstrate sufficient provider networks to meet demand, before permission for an expansion is granted.

D. Transportation assistance (§ 438.208)

A large body of scientific literature documents that transportation barriers prevent poor Americans from receiving needed health care.[73] The January final rule required that each plan develop a care coordination system that "has in effect procedures to address factors (such as a lack of transportation) that may hinder

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[72] 42 C.F.R. § 422.112(a)(5).

[73] *See, e.g*, Glenn Flores, Milagros Abreu, M. Olivar, Beth Kastner, *Access Barriers to Health Care for Latino Children*, Archives in Pediatrics and Adolescent Medicine, 1119-25 (November 1998).

enrollee adherence to prescribed treatments or regimens."

Without explanation, this provision has been removed from the proposed rule. As a result, plans have no responsibilities to address factors that may prevent access to care. The absence of such a provision undermines the rights that are provided; if patients cannot even get to the doctor's office, other services and protections are moot.

> **Section 438.208**: A provision should be added to require plans to have in effect procedures to address factors, such as a lack of transportation, that may hinder enrollee access to health care treatments or regimens.

E. Paperwork (§ 438.210)

Over the last decade, managed care plans have increased the "hassle factor" of physicians as a mechanism to cut costs. The January final rule guarded against this problem by ensuring that all requests for authorizations "not have information requirements that are unnecessary or unduly burdensome for the provider or the enrollee." Such a step is essential to protecting patient rights, as any right can be made immaterial if one must fill out an avalanche of paperwork in order to exercise it.

The proposed rule, without explanation, drops this requirement. As a result, plans can use paperwork as a weapon to decrease appropriate utilization. This single omission could be used to undermine many other rights in the rule.

> **Section 438.210**: A provision should be added that ensures that information requirements for authorization are necessary and not unduly burdensome for the provider or the enrollee.

F. Authorizations (§ 438.210)

The January final rule guaranteed that authorization decisions in cases involving the "enrollee's life or health or ability to maintain, or regain maximum function" must be made within 72 hours. The 72-hour deadline is also present in H.R. 2563, the managed care bill of rights legislation passed by the House and supported by President Bush.[74]

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[74]H.R. 2563, § 102(b)(1)(B).

Yet without explanation, the proposed rule sets a standard of "three working days" for expedited reviews and allows an extension for up to 14 days. We recognize that plans are still required to make a determination "as expeditiously as the enrollee's health condition requires." However, it is often difficult for plans to assess what the enrollee's health condition requires; regardless of the views of the treating physician, the plan's reviewers may take a position that an enrollee's health condition requires no immediate decision. The plan may then delay action over a long weekend or even obtain an extension of 14 days. The new provision, then, substantially weakens the rights of the patients.

> **Section 438.210**: The provision on expedited authorization decisions should be altered to assure that all such decisions are made as expeditiously as the enrollee's health condition requires or no later than 72 hours after the receipt of the request for service.

G. Public Notice of Sanctions (§ 438.724)

The January final rule required that state sanctions of MCOs must be published in local newspapers. This requirement is deleted arbitrarily, without explanation, in the proposed rule.

We believe that as with nursing homes overseen by CMS,[75] public notification of sanctions is essential for enrollees to make an informed choice between competing plans. The usefulness of all patient rights is called into question when patients and families are unaware that plans may have a record of violating these rights.

> **Section 438.724**: A provision should be added to require states to publish notice of sanctions in local newspapers of wide circulation with 30 days after imposing the sanctions.

[75] *See, e.g.,* published deficiencies found in nursing homes on the CMS web site (http://www.hcfa.gov/medicaid/ltchomep.htm).